

REMARKS

This is a Response to the Office Action mailed May 30, 2003. Claims 1-19 are pending in the application. Claims 1-16 have been rejected by the Examiner. As noted above, Applicants have amended Claims 1, 3-6, 8, 13 and 14, and added New Claims 17-19. The amendments and New Claims 17-19 are fully supported by the written description. Also, no new matter has been introduced into the application. The numbered paragraphs below correspond to the Examiner's numbered paragraphs.

Claim Rejections – 35 USC § 103

1./2. Claims 1, 6, 7, 8 14 and 15 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Wink et al. (WO 94/02845) in view of Hammarström et al. (USPN 6,336,906). Wink et al. is directed to an electrode sensor that can be used to measure nitric oxide concentration in solution (see abstract). Wink et al. disclose that the electrode sensor can have an “electrochemically active polymeric coating which interacts with NO in such a manner so as to cause a change in the redox potential of NO and the electrode sensor” (pages 7 and 8). However, Wink et al. clearly fail to disclose that the electrode sensor is included in an elongated wire assembly.

Hammarström et al. is directed to a sensor and guide wire assembly for intravascular pressure measurements having improved handling properties in the vessels in which it is to be inserted (see col. 1, lines 8-11). Hammarström et al. disclose that the assembly includes an enlarged portion with a sensor receptacle and a sensor mounted therein. The enlarged portion is meant to decrease the stress exerted on the sensor during sharp vessel turns (see col. 4, lines 21-23). Hammarström et al. also disclose that the sensor is attached to signal transmitting cables,

and that the “cables 14 are, for example, attached to the sensor 12 on bond pads (not shown) by bonding or by another suitable technique. The points of attachment of the cables 14 to the sensor 12 are preferably **protected from the environment, i.e., from blood or other body fluids**. Normally, this may be achieved by filling the slot 11 with silicon rubber or other polymer material to provide adequate protection from such fluids and other environmental impact” (col. 4, lines 47-55) (emphasis added).

To establish *prima facie* obviousness, **all of the claimed limitations** must be taught or suggested in the references cited. *In re Royka*, 490 F.2d 981 (CCPA 1974). Wink et al. and Hammarström et al., alone or in combination, fail to teach or suggest all of the claimed limitations of the present invention. For instance, referring to amended Claim 1, the prior art references fail to disclose a guidewire that includes

- (a) an elongated wire assembly capable of being guided to a designated region of a vessel within a patient’s body, the elongated wire assembly comprising a core section including a lumen disposed along a length of the core section, and **an opening in the core section, the opening positioned so that the lumen is in fluid communication with the vessel; and**
- (b) a sensor positioned within the lumen of the core section so that the sensor is in fluid communication with the vessel through the opening, the sensor being capable of measuring the level of nitric oxide or superoxide molecules in the vessel of the patient’s body.

In particular, the prior art references at least fail to disclose a sensor positioned in a lumen of a wire assembly that is in fluid communication with body fluids through a opening in the wire assembly. Instead, the prior art teaches that sensors should be protected from the environment. Specifically, Hammarström et al. clearly disclose that the sensor is **protected from the environment, i.e., from blood or other body fluids** (see col. 4, lines 50-52). Because the cited references do not disclose **all of the limitations** of amended Claim 1, Claim 1 is allowable over

Wink et al. in view of Hammarström et al. Claims 6 and 7 depend directly from Claim 1, and should be allowable for at least the same reason.

Additionally, Wink et al. and Hammarström et al., alone or in combination, fail to teach or suggest all of the limitations of amended Claim 8. In particular, the prior art references fail to disclose a method that includes

- (a) positioning an elongated wire assembly into a vessel, the wire assembly including
 - a core section including a lumen disposed along a length of the core section,
 - an opening in the core section, the opening positioned so that the lumen is in fluid communication with the vessel, and**
 - a sensor positioned within the lumen of the core section so that the sensor is in fluid communication with the vessel through the opening, the sensor being capable of measuring the level of nitric oxide or superoxide in the vessel;**
- (b) guiding the wire assembly to a designated region within the vessel;
- (c) **allowing body fluids to enter the lumen through the opening in the core section so that the body fluids are in contact with the sensor; and**
- (d) **measuring the level of nitric oxide or superoxide of the body fluids in contact with the sensor.**

The prior art references at least fail to disclose a method that includes exposing a sensor to body fluids in order to measure the level of nitric oxide or superoxide of the body fluids in contact with the sensor. As noted above, the prior art teaches just the opposite—that the sensors should be protected from the environment (see, Hammarström et al., col. 4, lines 50-52). Since Wink et al. and Hammarström et al., alone or in combination, fail to disclose all of the limitations of amended Claim 8, Claim 8 is allowable over Wink et al. in view of Hammarström et al. Claims 14 and 15 depend directly from Claim 8, and should be allowable for at least the same reason.

3. Claims 1-5, 7-9, 11, 13 and 15 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Soller (USPN 5,582,170) in view of Hammarström et al. (USPN 6,336,906). Soller is directed to a fiber optic sensor for measurement of in vivo nitric oxide

concentrations in a subject. The sensor contains a nitric oxide-sensing compound in a polymer matrix attached to an optical fiber (see abstract). Soller clearly fails to disclose that the sensor is included in an elongated wire assembly.

Soller and Hammarström et al., alone or in combination, fail to teach or suggest all of the claimed limitations of the present invention. In particular, the prior art references at least fail to disclose all of the limitations of amended Claim 1, such as a wire assembly including an opening in a lumen positioned so that the lumen is in fluid communication with the vessel, and a nitric oxide sensor positioned so that the sensor is in fluid communication with the vessel through the opening. Instead, Hammarström et al. clearly disclose that the sensor is **protected from the environment, i.e., from blood or other body fluids** (see col. 4, lines 50-52). Because the prior art does not disclose **all of the limitations** of amended Claim 1, Claim 1 is allowable over Soller in view of Hammarström et al. Claims 2-5 and 7 depend directly or indirectly from Claim 1, and should be allowable for at least the same reason.

Furthermore, the prior art references fail to disclose all of the limitations of amended Claim 8, including a method comprising exposing a sensor to body fluids in order to measure the level of nitric oxide or superoxide of the body fluids in contact with the sensor. As noted above, the prior art teaches that the sensors should be protected from the environment (see, Hammarström et al., col. 4, lines 50-52). Since Soller and Hammarström et al., alone or in combination, fail to disclose all of the limitations of amended Claim 8, Claim 8 is allowable over Soller in view of Hammarström et al. Claims 9, 11, 13 and 15 depend directly or indirectly from Claim 8, and should be allowable for at least the same reason.

4. Claims 10, 12 and 16 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Soller in view of Hammarström et al. and further in view of Cooke et al.

(USPN 5,945,452). As noted above, Claim 8 is allowable over Soller in view of Hammarström et al. The disclosure of Cooke et al. does not cure the deficiencies of these prior art references as related to Claim 8. Accordingly, Claim 8 is allowable over Soller in view of Hammarström et al. and further in view of Cooke et al. Claims 10, 12 and 16 depend directly or indirectly from Claim 8, and are allowable for at least the same reason.

CONCLUSION

Claims 1-16 are pending in this application. Examination and allowance of the claims are respectfully requested. If the Examiner has any questions or concerns, the Examiner is invited to telephone the undersigned attorney at (415) 954-0345.

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Respectfully submitted,

A handwritten signature in black ink, appearing to read 'Paul J. Meyer, Jr.', is written over a horizontal line.

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